UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

March 5, 2014

MEMORANDUM

Subject:	Name of Pesticide Product:	CERTISHIELD FOR DOGS
	EPA Reg. No. /File Symbol:	65331-8
	DP Barcode:	DP 418240
	Decision No.:	480831
	Action Code:	R340
	Submission #:	938212
	E-Sub#:	--
	PC Codes:	109701 (Permethrin: 44.88%) 129121 (Fipronil: 6.01%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
March-5-2014

To: Linda DeLuise/Richard Gebken, RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: MERIAL LIMITED

FORMULATION FROM LABEL:

Active Ingredient(s):	by wt.
109701 Permethrin	44.88%
129121 Fipronil	6.01%
Other Ingredient(s):	49.11%
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

"…Attached is an addendum to the adult CASS study 49172310."

BACKGROUND:

The registrant has submitted a response (MRID 49271301: titled "ADDENDUM TO MRID 49172310") to a TRB review (TXR 5014668) dated December 4, 2013.

COMMENTS AND RECOMMENDATIONS:

1. The TRB review of December 4, 2013 included the following:

   This companion animal safety study in adult dogs is currently classified as unacceptable and **does not satisfy** the guideline requirement for a companion animal safety study (OPPTS 870.7200) in dogs. It can be upgraded to acceptable if 1) the registrant provides sufficient information regarding the method of dosing and application sites, and 2) adequately addresses the factors that may have been involved in the occurrence of signs of toxicity that occurred in two 5X females following the first application but not in subsequent treatments.

2. The registrant has responded (MRID 49271301) with the following (as an addendum to Section E. Treatment Administration, of the final study report):

   All treatments were applied by parting the hair and applying the formulation directly onto the skin using either a 3 or 6 mL syringe as needed to administer the designated amount. The volume at each application was divided into two approximately equal volumes. Both fractions were place[d] on the midline of the neck. One fraction was applied between the base of the skull and the shoulder blades and the other fraction was applied at the front of the shoulder blades."

3. This response adequately meets the first condition for an upgrade of the study to acceptability. However, it does not satisfy the second ("adequately addresses the factors that may have been involved in the occurrence of signs of toxicity that occurred in two 5X females following the first application but not in subsequent treatments.)" The study in MRID 49172310 remains classified as unacceptable.